# REMARKS

Claims 180-222 are currently pending in the application.

#### Substance of Interview

Applicants appreciate the Examiner's courtesy in allowing Applicants and Applicants' Representatives to conduct a Personal Interview at the USPTO on July 25, 2006. During this Interview, Applicants submitted arguments traversing the rejection of claims 196 and 218 under 35 USC §103(a) and claims depending therefrom. Applicants argued that inserting an open reading frame from a target viral genome within a gene start and gene end sequence of a background viral genome is not an obvious modification of US Patent No. 5,869,036 to Belshe *et al.* ("Belshe"), as the Examiner alleged. Applicants argued that Belshe does not disclose, teach or suggest the transcription signals of viral genomes. Moreover, merely swapping one ORF for another as taught, allegedly, by Belshe will rarely result in virus recovery because the inserted polynucleotide must conform to the "Rule of Six." That is, the number of nucleotides in the inserted polynucleotide must be a multiple of six for viral recovery to occur. In response to the arguments, the Examiner stated that she would reconsider the rejection. In a follow-up teleconference on August 7, 2006, the Examiner appeared to agree that Applicants' arguments are sufficient to overcome the rejection.

Applicants also submitted arguments during the interview traversing the §112, first paragraph, rejection of claims 190 and 213 and claims depending therefrom. In the present Office Action, the Examiner rejected the claims for recitation of the genus "said partial or complete PIV genome or antigenome including a mutation encoding a substitution of amino acid 456 of the L protein by another amino acid", stating that the Applicants were not in possession of the claimed genus at the time of filing.

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During the interview, Applicants stated that a skilled artisan is able to envision the 20 amino acids that may be located at position 456 of the L protein, therefore Applicants were in possession of the claimed genus. Moreover, Applicants stated that even if the rejection is more properly stated as an enablement rejection because it is not immediately clear what substitutions are operable, the rejection is still improper because a skilled artisan is amply guided by the specification to routinely determine which embodiments are operable.

The Examiner's alleged that the specification does not disclose a nexus between the *type* of amino acid substituted (e.g. hydrophilic amino acids) and attenuation. In response, Applicants submitted that the specification does disclose a nexus between the location of the amino acid substitution and attenuation. (See, e.g. page 57, line 8, through to page 58, line 8 in the specification as filed). The Examiner stated she would reconsider this rejection. In a follow-up teleconference on August 7, 2006, the Examiner agreed to withdraw the §112, first paragraph rejection.

#### **Information Disclosure Statement**

Applicants are concurrently e-filing an Information Disclosure Statement (IDS) with this response. Applicants request that the Examiner acknowledge the Information Disclosure Statement concurrently filed and initial a copy of the PTO-1449 form.

### Claim Rejection-35 USC § 112, first paragraph

Claims 190-195 and 213-217 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. As stated *supra*, the Examiner agreed on August 7, 2006, in a teleconference with Applicants' representatives to withdraw the rejection. Accordingly, this rejection is overcome.

## Claim Rejection-35 USC § 103

The Examiner has rejected claims 196, 198, 200, 201, 202, 218, 220 and 222 under 35 USC §103(a) as allegedly obvious over Belshe. Applicants respectfully traverse.

In order to establish *prima facie* obviousness, the combined references must teach or suggest all of the elements of a claim. Independent claims 196 and 218 and claims dependent thereon, are drawn to isolated viruses comprising a PIV genome (or antigenome) and polynucleotides, respectively, wherein the genomes or polynucleotides encode a heterologous antigenic determinant that is located between a gene start and a gene end sequence.

The Belshe reference fails to disclose, teach or suggest each and every element of claims 196 and 218. Particularly, Belshe fails to teach or suggest the elements of a "gene start sequence" and a "gene end sequence." Thus, Belshe cannot be said to suggest substitution of only an open reading frame between such gene start and gene end sequences.

Therefore, because each and every element of claims 196 and 218 are not taught or suggested by Belshe, claims 166 and 201 are not obvious over Belshe. Likewise, claims 198, 200, 201, 202, 218, 220 and 222 are allowable at least by virtue of dependency. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

## Rejection under non-statutory double-patenting

09/083, 793

Claims 180-222 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 144-215 of copending Application No. 09/083, 793.

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Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/458, 813

Claims 180-222 are provisionally rejected on the on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53-85 of copending Application No. 09/458, 813.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/459, 062

Claims 180-222 are provisionally rejected on the ground of nonstatutory obviousnesstype double patenting as being unpatentable over claims 1-30 and 46-74 of copending Application No. 09/459, 062.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/586, 479

Claims 180-222 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 84-163 of copending Application No. 09/586,479.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

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The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is

respectfully requested.

In view of the above amendment, applicant believes the pending application is in

condition for allowance.

Should there be any outstanding matters that need to be resolved in the present

application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. .) at the

telephone number of the undersigned below, to conduct an interview in an effort to expedite

prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies

to charge payment or credit any overpayment to Deposit Account No. Error! Unknown document

property name. for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly,

extension of time fees.

Dated:

Respectfully submitted,

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Attachment: Terminal Disclaimer